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JUN - 7 2004

We are

Endoscopy
Smith & Nephew, Inc.
130 Forbes Blvd
Mansfield, MA 02048

508 261 3600
508 261 3616 fax
www.smith-nephew.com

## VI. 510(k) SUMMARY
**Smith & Nephew™ ULTRABRAID™ Suture**
**Date Prepared: May 7, 2004**

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

### A. Submitter

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

### B. Company Contact

Denise Lima
Regulatory Affairs Specialist

### C. Device Name

| | |
|---|---|
| Trade Name: | Smith & Nephew™ ULTRABRAID™ Suture |
| Common Name: | Nonabsorbable Surgical Suture |
| Classification Name: | Polyethylene Nonabsorbable Surgical Suture |

### D. Predicate Devices

The Smith & Nephew ULTRABRAID™ Suture is substantially equivalent in design, materials, function and intended use to the following devices in commercial distribution: Teleflex Medical, Force Fiber™ Polyethylene Nonabsorbable Surgical Suture, K033654 and Teleflex Medical, Force Fiber™ Blue Co-Braid Polyethylene Nonabsorbable Surgical Suture, K040472.

### E. Description of Device

The Smith & Nephew™ ULTRABRAID™ Suture is a nonabsorbable, sterile, surgical suture composed of either white ultra high molecular weight (UHMW) Polyethylene or white UHMW Polyethylene cobraid with blue monofilament polypropylene. ULTRABRAID suture is provided braided and undyed. ULTRABRAID sutures are USP except for diameter.

## F. Intended Use

Smith & Nephew ULTRABRAID Suture is indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries.

## G. Comparison of Technological Characteristics

The Smith & Nephew ULTRABRAID suture has the same technological characteristics and materials as the predicate devices identified above. The product design is in conformance with the consensus standards identified in this submission. The Smith & Nephew ULTRABRAID sutures only differ from the predicate device in suture tipping to stiffen the suture ends.

Denise Lima 5/7/04

Denise Lima
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Ms. Denise Lima
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K041216
Trade/Device Name: Smith & Nephew™ ULTRABRAID™ Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable suture
Regulatory Class: II
Product Code: GAT
Dated: May 7, 2004
Received: May 10, 2004

Dear Ms. Lima:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhous

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041216

**INDICATIONS FOR USE STATEMENT**

510(K) Number: (if known)

Device Name: Smith & Nephew™ ULTRABRAID™ Suture

Indications For Use: Smith & Nephew ULTRABRAID Suture is indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries.

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K041216